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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/335,363	06/17/1999	GEORGE SHIBATA	39D-1884	6398

7590 08/12/2003

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/335,363

Applicant(s)

SHIBATA ET AL.

Examiner

LaToya L. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 20-27 is/are rejected.
- 7) ☒ Claim(s) 15-19 and 28-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Office Action is in response to Applicants' remarks filed on May 23, 2003 and entered as Paper No. 24. Claims 1-34 are pending.

Withdrawal of Rejections from Previous Office Action

- The rejection of claims 27-32 under 35 USC 112, second paragraph is withdrawn in view of Applicants' explanation that claim 27 is dependent on claim 26, which introduces the "belt" feature.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-11, 13, 14, 20-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Stylli et al.

Styli et al teach an automated analyzer system comprising a storage and retrieval module that receives and stores a plurality of primary chemical plates in a storage means 300 (e.g. primary sample tubes). This storage and retrieval module includes a carriage mechanism 130 which grips the primary chemical plate (col. 11, line 59 – col. 12, line 3; col. 19, line 20 – col. 20, line 19; figure 3) and transfers the primary chemical plate to a continuous, bi-directional

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sample transporter 310 (e.g. continuous transport) which is operably connected to a sampling distribution station. Note: the sample transport can include a plurality of conveyor means or articulated robotic arms used to grip the plates (col. 17, lines 46-60; col. 23, lines 12-18). Moreover, the bi-directional sample transport 310 can return the chemical plates back to the storage and retrieval unit. The sample distribution station includes a plurality of sampling probes to transfer a volume of sample from a primary chemical plate 34 to a secondary, daughter multiwell plate, (e.g. secondary sample tube) with a higher density (col. 12, lines 4-64). The sample distribution station can be mechanically linked to a plurality of reaction modules or workstations (e.g. first and second analyzers) (col. 17, lines 60-67). Styli et al teach the use of a plurality of lift and transfer mechanisms 315 (e.g. tube transfer stations) adapted to move the sample plates from the sample transport mechanism to one of the plurality of reaction modules or workstations (col. 2, lines 20-33). Styli et al teach the use of a supervisory controller for receiving sample identification information and issuing a sample testing procedure such that the instrument is capable of performing different assays, each of such assays having different protocols (col. 28, line 49 – col. 36, line 67). Each chemical in the master table is also represented in an aliquots table 607. The creation of aliquots from any chemical managed by the system may be in any format and is not limited to multi-well plates. A chemical may be individually tracked, or become part of a master configuration where it is present with a plurality of other chemicals, in which case the group, rather than a single chemical can be tracked by the system. Each tracked entity (e.g. work unit) is recorded as an entry in format table 608. The current location of each tracked entity is stored along with its identification in the table that represents that entity. Typical formats can include tubes and bottles of various capacities, arrays of wells as in the various multi-well plates, or any other

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format desired. Any chemical or group of chemicals stored in a format can be identified, e.g. by a unique bar code label (col. 30, lines 42-59).

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stylli et al in view of Kurosaki et al.

Stylli et al, as discussed above, teach the creation of aliquots from any chemical managed by the system may be in any format and is not limited to multi-well plates. Typical formats include tubes and bottles of various capacities, arrays of wells as in the various multi-well plates, or any other format desired. However, Stylli et al fail to specifically recite a sample probe comprising a cap piercer for removing liquid from a primary sample without removing the cap from the primary sample tube. However, the use of cap piercing probes is considered conventional in the art, see Kurosaki et al. Kurosaki et al teach an automatic analyzer which comprises a probe 12 for aspirating part of a sample from a sample tube 4 and dispensing into a reaction tube 8 (col. 3, line 63 – col. 4, line 7).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated in the system of Stylli et al the piercing probe, as taught by Kurosaki et al, in order to aspirate the contents of the sample vial without exposing the sample to possible environmental contaminants.

Allowable Subject Matter

5. Claims 15-19 and 28-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter:

The instant claims are drawn to a clinical chemistry system which includes a storage station, a sampling station with sample probe, a carriage mechanism for gripping a primary tube and providing it to the sampling station. Additionally, the system includes a first and second secondary tube transfer means for removing the secondary tubes from the continuous transport means and providing the secondary tubes to a corresponding analyzer. While numerous of such clinical analyzer systems exist, none of the prior art teaches a clinical chemistry system which includes a storage station, a sampling station with sample probe, a carriage mechanism for gripping a primary tube and providing it to the sampling station, a first and second secondary tube transfer means for removing the secondary tubes from the continuous transport means and providing the secondary tubes to a corresponding analyzer, where the continuous transport means comprises a continuous belt and a plurality of secondary tube carriages mounted to the belt which are adapted for carrying the secondary tube and provides lateral access to the secondary tube from at least two sides.

Response to Arguments

7. Applicant's arguments filed May 23, 2003 have been fully considered but they are not persuasive. Applicants argue that Stylli et al fail to teach a gripper that grips and transports

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the primary sample tube to the sampling station. Applicants point to col. 10, lines 46-49, and contend that the references teaches against using robotic hands that grip plates.

In response, the Examiner does not consider the reference's statement regarding robotic hands gripping plates as teaching away from the claimed invention. The statement is more of a non-preferred embodiment. In fact, as explained in the rejection, Stylli et al teach at col. 23, lines 12-17, that the sample transport means may include conveyor belts, robotic arms, slide mechanisms, guided vehicles and the like. Stylli et al **prefers** using conveyor belts, however, non-preferred embodiments do constitute prior art. "A reference may be relied upon for all that it would have reasonably suggested to one of ordinary skill in the art, including non-preferred embodiments", Merck & Co. v. Biocraft Laboratories, 874 F.2d 804. Furthermore, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments, In re Susi, 440 F.2d 442. Thus, although Stylli et al prefer using conveyor belts, the reference does not teach away from using robotic arms to grip the plates. The reference teaches robotic arms as an option, even though non-preferred. Further, contrary to Applicants' contention, the reference does teach robotic arms as sample transporting means at col. 23, lines 12-17. Therefore, the rejection is maintained.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory

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period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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August 7, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700